STATISTICAL ANALYSIS PLAN

STUDY TITLE: Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of the Efficacy and Safety of Intravenous Pamrevlumab, a Monoclonal Antibody Against Connective Tissue Growth Factor (CTGF), in Hospitalized Patients with Acute COVID-19 Disease

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CONFIDENTIALITY STATEMENT

SIGNATURE PAGE

Approvals

I have reviewed and accepted the information in this document to be a true and accurate representation of the Statistical Analysis Plan.

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LIST OF ABBREVIATIONS

AE	Adverse Event
ALP	Alkaline Phosphatase
ARDS	Acute Respiratory Distress Syndrome
AST	Aspartate Aminotransferase
ALT	Alanine Aminotransferase
ANOVA	Analysis of Variance
AST	Aspartate Aminotransferase
ATC	Anatomical Therapeutic Class
BMI	Body Mass Index
BSA	Body Surface Area
CI	Confidence Interval
CRF	Case Report Form
CTCAE	Common Terminology Criteria for Adverse Events
CTGF	Connective Tissue Growth Factor
DMC	Data Monitoring Committee
DBP	Diastolic Blood Pressure
DMP	Data Management Plan
ECG	Electrocardiogram
EOS	End of Study
EOT	End of Treatment
HAHA	Human Anti-Pamrevlumab Antibody
ICH E9	International Conference on Harmonization Statistical Principles for Clinical Trials
ITT	Intent-To-Treat
IV	Intravenous
LLN	Lower Limit of Normal, value provided by the laboratory
MAR	Missing At Random
MedDRA	Medical Dictionary for Regulatory Activities
NIAID	National Institute of Allergy and Infectious Diseases

PCS	Potentially Clinically Significant
PT	Preferred Term
SMQ	Standardized MedDRA Queries
SOC	System Organ Class
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SBP	Systolic Blood Pressure
TEAE	Treatment Emergent Adverse Event
TESAE	Treatment Emergent Serious Adverse Event
TLF	Table, Listing, and Figure
ULN	Upper Limit of Normal, value provided by the laboratory
WHODD	World Health Organization Drug Dictionary
WHO	World Health Organization

1 INTRODUCTION

The study was terminated by Sponsor on February 19, 2021. Twenty-two subjects were randomized for the study at the study termination. This statistical analysis plan (SAP) provides a more detailed elaboration of the analyses.

2 STUDY OBJECTIVE

To assess the efficacy and safety of intravenous pamrevlumab, an investigational monoclonal antibody against connective-tissue growth factor (CTGF), compared to placebo, in hospitalized patients with acute COVID-19 disease due to confirmed SARS-COV-2 infection.

3 STUDY DESIGN

This is a randomized, double-blind, placebo-controlled phase 2 study of the efficacy and safety of intravenous pamrevlumab, a monoclonal antibody against connective-tissue growth factor (CTGF), in hospitalized subjects with acute COVID-19 disease due to SARS-CoV-2 infection.

Eligible subjects are those with documented SARS-CoV-2 infection, age 40 to 85 years, with evidence of respiratory compromise requiring hospital admission. This age range is chosen to enhance detection of potential clinical benefits in subjects at highest risk for developing severe COVID-19 disease in this proof-of-concept study.

The total sample size is approximately 130 subjects. Subjects are randomized in a 1:1 ratio, according to a pre-determined randomization list from a permuted block design, to receive either pamrevlumab or placebo. All subjects are treated with standard-of-care according to the judgment of the Investigator.

Study drug is administered as IV infusion on Days 1 (day of randomization), 7, 14 and 28. A follow-up visit is performed 4 weeks after the last dose.

4 ENDPOINTS

4.1 Primary Efficacy Endpoint

The primary endpoint is the proportion of subjects who never received mechanical ventilation and/or ECMO and alive at Day 28.

4.2 Secondary Efficacy Endpoints

- Proportion of subjects alive, discharged home, and not on supplemental oxygen at Day 28
- Proportion of subjects who never received mechanical ventilation and/ or ECMO and alive at Day 14
- Time to recovery by Day 28 based on the NIAID 8-point ordinal scale (Day of recovery is defined as the first day on which the patient satisfies one of the following three

categories from the ordinal scale: (1) Not hospitalized, no limitations on activities; (2)Not hospitalized, limitations on activities and/or requiring home oxygen; (3) Hospitalized, not requiring supplemental oxygen, no longer requiring medical care (used if hospitalization was extended for infection-control reasons)

- Clinical status based on the NIAID 8-point ordinal scale (time range: Days 1 to 28)
- Days in ICU/CCU (either on or off mechanical ventilation and/or ECMO) at Day 28
- Days on mechanical ventilation and/or ECMO at Day 28
- Time to mechanical ventilation/ECMO or all-cause mortality at Day 28
- All-cause mortality at Day 28 (proportion of subjects deceased)
- Time to death from any cause at Day 28
- Change in PaO_2/FiO_2 ratio as categorical variable using Berlin criteria for ARDS categorization (mild, moderate, severe) (time range: Days 1 to 28)
- Change in PaO_2/FiO_2 ratio as continuous variable (time range: Days 1 to 28)
- Change in resting SpO_2 adjusted by FiO_2 (time range: Days 1 to 28)
- Change in (non-invasive) oxygen supplementation requirements (time range: Days 1 to 28)

4.3 Safety Assessments

Treatment-emergent adverse events (TEAEs); treatment-emergent serious adverse events (TESAEs), including hypersensitivity/ anaphylactic reactions, and vital signs.

5 GENERAL STATISTICAL CONSIDERATIONS

All data collected will be included in the data listings. All analyses will be performed using SAS® Version 9.3 or higher.

5.1 Statistical Methodology

There will be no treatment comparison analysis performed for this early terminated study.

Baseline is defined as the last value on or before the first infusion.

Continuous variables will be summarized using descriptive statistics: n, mean, standard deviation (SD), standard error (SE), median, 25th and 75th percentile, minimum, and maximum. The 2-sided 95% confidence interval for the treatment group mean will be presented as appropriate. Categorical variables will be tabulated by frequency count and percentage. The confidence interval for the proportions for each treatment group will be calculated using the Clopper-Pearson method as appropriate.

The Clopper-Pearson exact 95% CIs for the dichotomous parameters will be from SAS FREQ procedures with option BINOMIAL (EXACT). The 95% CIs for means of normally distributed parameters will be from appropriate SAS procedures such as PROC MEANS.

Analyses will be performed using SAS® Version 9.3 or higher.

5.2 Analysis Populations

The study population is defined through inclusion/exclusion criteria to reflect the targeted patient population for study. The details of the inclusion/exclusion criteria can be found in the protocol.

5.2.1 Intent-to-Treat (ITT) Population

The ITT population is defined as all randomized subjects. Subjects will be analyzed according to the treatment as randomized.

5.2.2 Safety Population

The safety population is defined as all subjects who have received any study medication. Subjects will be analyzed according to the treatment as received.

5.3 Data Handling Rules and Presentation Specifications

The following general guidelines will apply to all statistical analyses and data presentations:

- Age (Years) = INTCK('YEAR', Birth Date, Date of Informed Consent,'C') where INTCK is a SAS function. Age groups are 18 to 64, 64 to 75, >=75
- Duration of Ventilation will be calculated as Ventilation Stop Date/Time – max(Ventilation Start Date/Time, Randomization Date [we will use 12:00 if no time available] or 1st Dose completion Date/Time)
- All reporting values (mean, SD, 95% CI, etc.) for continuous variables will have the same decimal places as the raw data.
- All percentages will be rounded to one decimal place and lined up by the decimal place. The percentage will be suppressed when the count is zero. All analysis statistics will have the same decimal place as the raw value. All duration of time will have 1 decimal place.
- Body weight, height and temperatures will be converted using the following formula:

  - kg = lb/2.2

  - cm = 2.54 x in

  - $^{o}C = (5/9) \times (^{o}F - 32)$

- Computation formulas:

  $BSA = [Weight^{0.425} (kg) * Height^{0.725} (cm)] \times .007184$

  $BMI = Weight (kg) / (Height (m))^2$

- Mean Arterial Pressure (MAP) will be derived using the following equation:

  MAP = (2/3) * DBP + (1/3) SBP
- For continuous variables that are recorded as "<X" or ">X", the value of "X" will be used in the calculation of summary statistics.
- All tables and listings will have a header showing "FibroGen, Inc.", the protocol number, date of the database transfer, and Page x of y. A footer will show the program file path/name, output file path/name, run date and run time.

6 SUBJECT ACCOUNTABILITY AND DISPOSITION

The number and percentage of subjects who are randomized, dosed, treatment prematurely discontinued, and completed the study will be summarized by treatment group. Reasons for premature discontinuation as recorded on the Study Disposition page of the CRF will be summarized.

7 DEMOGRAPHICS AND BASELINE CHARACTERISTICS

7.1 Demographics and Important Baseline Characteristics

Demographic parameters and important baseline characteristics will be summarized for ITT population by treatment arm. These include but are not be limited to age, age group, sex, ethnicity, race, weight, body-mass index (BMI), smoking status, and selective medical history.

Descriptive statistics (n, mean, standard deviation, median, 25-75th percentiles, minimum, and maximum) will be presented for continuous variables. Frequency distributions (number and percentage of subjects) will be presented for categorical variables.

Descriptive statistics of baseline efficacy assessments will be presented in their change from baseline tables.

7.2 Medical History

Medical history will be listed for the Safety population.

8 TREATMENTS AND MEDICATIONS

8.1 Prior and Concomitant Medications

The use of the prior and concomitant medications will be listed for the ITT population. The version of WHODRUG used to code the medication is stated in the data management plan (DMP).

Medications are classified into 2 categories:

1. Prior medications - medications that are stopped prior to the first study drug infusion

2. Concomitant medications - medications that are used concomitantly with the study drug, which includes all medications that started after or not stopped before the first infusion.

8.2 Study Drug Exposure

Duration of study drug exposure in days is calculated as: (last dose date – first dose date + 1). Duration of study drug exposure will be summarized as a continuous variable. The duration will also be tabulated by the following categories for the Safety population.

1 to 3 days

>3 to <=7 days

>7 to <=14 days

>14 days <=21 days

>21 days

Pamrevlumab infusion dose (in mg and mg/Kg), number of infusions during study, and interruptions during infusion and reason for interruptions will also be listed.

8.3 Compliance

The compliance will be presented as % of actual doses of infusion administered over the expected total dose of infusions during study for the safety population. That is, compliance = actual doses received / scheduled doses * 100%. Treatment compliance will be listed only.

9 EFFICACY ANALYSES

Efficacy data will be summarized descriptively based on observed data for the ITT population. There will be no imputation performed for the missing endpoint value.

9.1 Primary Efficacy Endpoint - Proportion of Subjects who Never Received Mechanical Ventilation and/or ECMO and Alive at Day 28

Proportion of subjects never received mechanical ventilation and/or ECMO and alive at Day 28 will be summarized based on observed data.

9.2 Proportion of Subjects Alive, Discharged, and not on Supplemental Oxygen, Proportion of Subjects who Never Received Mechanical Ventilation and/ or ECMO and Alive, and Proportion of Subjects Deceased

Proportion of subjects alive, discharged home, and not on supplemental oxygen at Day 28, proportion of subjects never received mechanical ventilation and/ or ECMO and alive at Day 14, and proportion of all-cause deaths at Day 28 will be summarized descriptively based on observed data.

9.3 Time to Recovery, Time to Mechanical Ventilation/ECMO or All-cause Mortality, and Time to death

- Time (number of days) from randomization to recovery by Day 28 based on NIAID 8-point ordinal scale where recovery is defined as the first day on which the patient satisfies one of the following three categories from the ordinal scale: (1) Not hospitalized, no limitations on activities; (2) Not hospitalized, limitations on activities and/or requiring home oxygen; (3) Hospitalized, not requiring supplemental oxygen, no longer requiring medical care (used if hospitalization was extended for infection-control reasons)

  Subjects without the event will be censored at the date of last NIAID 8-point ordinal scale assessment.

- Time (number of days) from randomization to mechanical ventilation/ECMO or all-cause mortality by Day 28

  For subjects who did not have the event, the last known assessment date of mechanical ventilation/ECMO use or survival status, whichever later will be defined as the censoring date.

- Time (number of days) from randomization to death from any cause by Day 28

  For subjects who are alive, the recorded date of last known alive, last contact date, or the date of the last clinic visit, whichever latest will be defined as the censoring date.

  The number of days of the above endpoints will be summarized descriptively as appropriate.

9.4 Clinical Status Based on the NIAID 8-point Ordinal Scale at Day 28

Proportion of subjects by response category on the NIAID 8-point ordinal scale will be summarized descriptively based on observed data at baseline and Day 28.

Order	Ordinal Level
1	Not hospitalized, no limitations on activities
2	Not hospitalized, limitations on activities and/or requiring home oxygen
3	Hospitalized, not requiring supplemental oxygen, no longer requiring medical care (used if hospitalization was extended for infection-control reasons)
4	Hospitalized, not requiring supplemental oxygen, requiring ongoing medical care (COVID-19-related or otherwise)
5	Hospitalized, requiring supplemental oxygen
6	Hospitalized, requiring high-flow oxygen, non-invasive mechanical ventilation, or both

7	Hospitalized, requiring invasive mechanical ventilation, extra-corporeal membrane oxygenation (ECMO), or both
8	Death
Missing	

9.5 Number of Days in ICU/CCU and Number of Days on Mechanical Ventilation and/or ECMO

Total number of days in ICU/CCU (either on or off mechanical ventilation and/or ECMO) at Day 28 and total number of days on mechanical ventilation and/or ECMO at Day 28 will be summarized descriptively.

9.6 Change in Categorical PaO_2/FiO_2 Ratio (Mild, Moderate, and Severe)

PaO2/FiO2 ratio will be defined as a categorical variable using Berlin criteria for ARDS categorization (mild, moderate, severe), where mild is PaO2/FiO2 from >200 to <=300, moderate is from 100 to <=200, and severe is <100. Proportion of subjects of each category at baseline and Day 28 will be summarized descriptively.

9.7 Change from Baseline in PaO2/FiO2 Ratio and Change from baseline in Resting SpO2/FiO2 at Day 28

Change from baseline in PaO2/FiO2 ratio at Day 28 and change from baseline in resting SpO2 adjusted by FiO2 (SpO2/FiO2) at Day 28 will be summarized descriptively.

9.8 Change in (Non-invasive) Oxygen Supplementation Requirements at Day 28

The non-invasive oxygen supplementation requirements include:
(1) No oxygen supplementation (including breathe room air or have been discharged from hospital)
(2) Non-invasive oxygen supplementation -nasal cannula and face-mask

Change in non-invasive oxygen supplementation requirements will be presented by proportion of subjects with non-invasive oxygen supplementation requirements at baseline and at Day 28.

10 SAFETY ANALYSES

The safety analyses will be based on the Safety population.

10.1 Adverse Events

Adverse events will be coded using the latest Medical Dictionary for Regulatory Activities (MedDRA), and the final version will be stated in the data management plan (DMP). Per protocol, the 28 days after the last dose is the last safety follow up. Therefore, the treatment emergent adverse event (TEAE) is defined as an adverse event (AE) with an onset date on or after the first infusion up to within 28 days from the last infusion date. An AE with missing start date/time will be considered to be a TEAE.

The number (%) of subjects reporting TEAEs in each treatment group will be summarized by system organ class and preferred term; by system organ class, preferred term, and severity; and by system organ class, preferred term, and relationship to study medication. If more than one event occurs with the same SOC/preferred term for the same patient, the patient will be counted only once for that SOC/preferred term using the most severe and most related occurrence for the summarization by severity and by relationship to the study medication.

In addition, number (%) of subjects with treatment-emergent serious AEs (TESAE), number (%) of subjects with non-serious TEAE, number (%) of subjects with most frequent (non-serious) TEAE (>=5%), and number (%) of subjects with TEAE leading to discontinuation will be summarized by SOC/preferred term. The hypersensitivity and anaphylactic reactions will be listed.

Listings of subjects with serious adverse events (SAEs), subjects with adverse events leading to discontinuation, and subjects who died will be provided.

10.2 Vital Signs

The pre- and post-infusion vital signs (systolic and diastolic blood pressure (mmHg), respiration rate (breath/min), heart beat (beat/min), Temperature (C) will be listed for the safety population.

10.3 Laboratory Tests

No laboratory test results were collected.

11 INTERIM ANALYSIS

The study do not have interim analysis.

12 REFERENCE

E9 (R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials

APPENDIX I HANDLING MISSING/INCOMPLETE DATES

A. Handling Missing/Incomplete AE Onset Date

If the AE onset date is incomplete or missing, the following rules will be applied to impute AE onset date.

- If year and month are present, only day is missing,
  a) If AE onset Year/month = Day 1 Year/month, assign onset day = day of Day 1 (Day 1 is the first infusion day);
  b) If AE onset Year/month ≠ Day 1 Year/month, assign onset day = 1st of the month;
- If year is present, month and day are missing, or when only month is missing (treating day as missing),
  a) If AE onset year = year of Day 1, assign onset date = month and day part of Day 1 date;
  b) If AE onset year ≠ year of Day 1, assign onset date= January 1st.
- If onset date is completely missing, assign onset date = date of Day 1.

If the stop date is complete and the imputed start date as above is after the stop date, the start date will be imputed by the stop date.

B. Handling Missing/Incomplete Prior or Concomitant Medication Start/Stop Dates

For prior or concomitant medications, including rescue medications, incomplete (i.e., partially missing) start date is imputed the same way as for the AE described above. When the start date and the stop date are both incomplete for a patient, impute the start date first.

Incomplete Stop Date

The following rules are applied to impute the missing stop date, if needed.

- If year is present, month and day are missing, or when only month is missing (treating day as missing)
  a) If stop year = year of last dose, assign stop date = month and day of the last dose date;
  b) If stop year ≠ year of Day 1, assign stop date= December 31st.
- If year and month are present, only day is missing,
  a) If AE stop Year/month = Year/month of last dose date, assign stop day = day part of last dose date
  b) If AE stop Year/month ≠ Day 1 Year/month, assign onset day = last day of the month;
- Impute CM end date even if 'ONGOING' is checked so as to report the CM treatment duration in the study if needed.

APPENDIX II STANDARDIZED MEDDRA QUERIES (SMQ) FOR HYPERSENSITIVITY REACTION

MedDRA 23.0: Hypersensitivity (SMQ) Preferred Term	Code	Scope	Addition Version	Last Modified Version
Acquired C1 inhibitor deficiency	10081035	Narrow	21.0	21.0
Acute generalised exanthematous pustulosis	10048799	Narrow	16.0	16.0
Administration related reaction	10069773	Narrow	20.1	20.1
Administration site dermatitis	10075096	Narrow	18.1	18.1
Administration site eczema	10075099	Narrow	18.1	18.1
Administration site hypersensitivity	10075102	Narrow	17.1	17.1
Administration site rash	10071156	Narrow	16.0	16.0
Administration site recall reaction	10075964	Narrow	18.1	18.1
Administration site urticaria	10075109	Narrow	17.1	17.1
Administration site vasculitis	10075969	Narrow	18.0	18.0
Allergic bronchitis	10052613	Narrow	16.0	16.0
Allergic colitis	10059447	Narrow	16.0	16.0
Allergic cough	10053779	Narrow	16.0	16.0
Allergic cystitis	10051394	Narrow	16.0	16.0
Allergic eosinophilia	10075185	Narrow	17.1	17.1
Allergic gastroenteritis	10075308	Narrow	17.1	17.1
Allergic hepatitis	10071198	Narrow	16.0	16.0
Allergic keratitis	10057380	Narrow	16.0	16.0
Allergic oedema	10060934	Narrow	16.0	16.0
Allergic otitis externa	10075072	Narrow	17.1	17.1
Allergic otitis media	10061557	Narrow	16.0	16.0
Allergic pharyngitis	10050639	Narrow	16.0	16.0
Allergic reaction to excipient	10078853	Narrow	20.0	20.0
Allergic respiratory disease	10063532	Narrow	16.0	16.0
Allergic respiratory symptom	10063527	Narrow	16.0	16.0
Allergic sinusitis	10049153	Narrow	16.0	16.0
Allergic stomatitis	10079554	Narrow	20.1	20.1
Allergic transfusion reaction	10066173	Narrow	16.0	16.0
Allergy alert test positive	10075479	Narrow	18.0	18.0
Allergy test positive	10056352	Narrow	16.0	16.0
Allergy to immunoglobulin therapy	10074079	Narrow	16.1	16.1
Allergy to surgical sutures	10077279	Narrow	19.0	19.0

Allergy to vaccine	10055048	Narrow	16.0	16.0
Anal eczema	10078682	Narrow	19.1	22.1
Anaphylactic reaction	10002198	Narrow	16.0	16.0
Anaphylactic shock	10002199	Narrow	16.0	16.0
Anaphylactic transfusion reaction	10067113	Narrow	16.0	16.0
Anaphylactoid reaction	10002216	Narrow	16.0	16.0
Anaphylactoid shock	10063119	Narrow	16.0	16.0
Anaphylaxis treatment	10002222	Narrow	16.0	16.0
Angioedema	10002424	Narrow	16.0	16.0
Antiallergic therapy	10064059	Narrow	16.0	16.0
Antiendomysial antibody positive	10065514	Narrow	16.0	16.0
Anti-neutrophil cytoplasmic antibody positive vasculitis	10050894	Narrow	16.0	16.0
Application site dermatitis	10003036	Narrow	16.0	16.0
Application site eczema	10050099	Narrow	16.0	16.0
Application site hypersensitivity	10063683	Narrow	16.0	16.0
Application site rash	10003054	Narrow	16.0	16.0
Application site recall reaction	10076024	Narrow	18.1	18.1
Application site urticaria	10050104	Narrow	16.0	16.0
Application site vasculitis	10076027	Narrow	18.0	18.0
Arthritis allergic	10061430	Narrow	16.0	16.0
Aspirin-exacerbated respiratory disease	10075084	Narrow	17.1	17.1
Atopic cough	10081492	Narrow	21.1	21.1
Atopy	10003645	Narrow	16.0	16.0
Blepharitis allergic	10005149	Narrow	16.0	16.0
Blood immunoglobulin E abnormal	10005589	Narrow	16.0	16.0
Blood immunoglobulin E increased	10005591	Narrow	16.0	16.0
Bromoderma	10006404	Narrow	16.0	16.0
Bronchospasm	10006482	Narrow	16.0	16.0
Bullous haemorrhagic dermatosis	10083809	Narrow	23.0	23.0
Catheter site dermatitis	10073992	Narrow	16.1	16.1
Catheter site eczema	10073995	Narrow	16.1	16.1
Catheter site hypersensitivity	10073998	Narrow	16.1	16.1
Catheter site rash	10052271	Narrow	16.0	16.0
Catheter site urticaria	10052272	Narrow	16.0	16.0
Catheter site vasculitis	10074014	Narrow	16.1	16.1
Chronic eosinophilic rhinosinusitis	10071399	Narrow	16.0	16.0
Chronic hyperplastic eosinophilic sinusitis	10071380	Narrow	16.0	16.0

Circulatory collapse	10009192	Narrow	16.0	16.0
Circumoral oedema	10052250	Narrow	16.0	16.0
Circumoral swelling	10081703	Narrow	21.1	21.1
Conjunctival oedema	10010726	Narrow	16.0	16.0
Conjunctivitis allergic	10010744	Narrow	16.0	16.0
Contact stomatitis	10067510	Narrow	16.0	16.0
Contrast media allergy	10066973	Narrow	16.0	16.0
Contrast media reaction	10010836	Narrow	16.0	16.0
Corneal oedema	10011033	Narrow	16.0	16.0
Cutaneous vasculitis	10011686	Narrow	16.0	16.0
Dennie-Morgan fold	10062918	Narrow	16.0	16.0
Dermatitis	10012431	Narrow	16.0	16.0
Dermatitis acneiform	10012432	Narrow	16.0	16.0
Dermatitis allergic	10012434	Narrow	16.0	16.0
Dermatitis atopic	10012438	Narrow	16.0	16.0
Dermatitis bullous	10012441	Narrow	16.0	16.0
Dermatitis contact	10012442	Narrow	16.0	16.0
Dermatitis exfoliative	10012455	Narrow	16.0	16.0
Dermatitis exfoliative generalised	10012456	Narrow	16.0	16.0
Dermatitis herpetiformis	10012468	Narrow	16.0	16.0
Dermatitis infected	10012470	Narrow	16.0	16.0
Dermatitis psoriasiform	10058675	Narrow	16.0	16.0
Device allergy	10072867	Narrow	19.0	19.0
Dialysis membrane reaction	10076665	Narrow	18.1	18.1
Distributive shock	10070559	Narrow	16.0	16.0
Documented hypersensitivity to administered product	10076470	Narrow	18.0	18.0
Drug eruption	10013687	Narrow	16.0	16.0
Drug hypersensitivity	10013700	Narrow	16.0	16.0
Drug provocation test	10074350	Narrow	17.0	17.0
Drug reaction with eosinophilia and systemic symptoms	10073508	Narrow	16.0	16.0
Eczema	10014184	Narrow	16.0	16.0
Eczema infantile	10014198	Narrow	16.0	16.0
Eczema nummular	10014201	Narrow	16.0	16.0
Eczema vaccinatum	10066042	Narrow	16.0	16.0
Eczema vesicular	10058681	Narrow	16.0	16.0
Eczema weeping	10055182	Narrow	16.0	16.0
Encephalitis allergic	10056387	Narrow	16.0	16.0
Encephalopathy allergic	10014627	Narrow	16.0	16.0

Eosinophilic granulomatosis with polyangiitis	10078117	Narrow	19.1	19.1
Epidermal necrosis	10059284	Narrow	16.0	16.0
Epidermolysis	10053177	Narrow	16.0	16.0
Epidermolysis bullosa	10014989	Narrow	16.0	16.0
Epiglottic oedema	10015029	Narrow	16.0	16.0
Erythema multiforme	10015218	Narrow	16.0	16.0
Erythema nodosum	10015226	Narrow	16.0	16.0
Exfoliative rash	10064579	Narrow	16.0	16.0
Eye allergy	10015907	Narrow	16.0	16.0
Eye oedema	10052139	Narrow	16.0	16.0
Eye swelling	10015967	Narrow	16.0	16.0
Eyelid oedema	10015993	Narrow	16.0	16.0
Face oedema	10016029	Narrow	16.0	16.0
Fixed eruption	10016741	Narrow	16.0	20.0
Giant papillary conjunctivitis	10018258	Narrow	16.0	16.0
Gingival oedema	10049305	Narrow	16.0	16.0
Gingival swelling	10018291	Narrow	16.0	16.0
Gleich's syndrome	10066837	Narrow	16.0	16.0
Haemorrhagic urticaria	10059499	Narrow	16.0	16.0
Hand dermatitis	10058898	Narrow	16.0	16.0
Henoch-Schonlein purpura	10019617	Narrow	16.0	16.0
Henoch-Schonlein purpura nephritis	10069440	Narrow	16.0	16.0
Heparin-induced thrombocytopenia	10062506	Narrow	16.0	16.0
Hereditary angioedema	10019860	Narrow	16.0	16.0
Hereditary angioedema with C1 esterase inhibitor deficiency	10080955	Narrow	21.0	21.0
Hypersensitivity	10020751	Narrow	16.0	16.0
Hypersensitivity myocarditis	10081004	Narrow	21.0	21.0
Hypersensitivity pneumonitis	10081988	Narrow	22.0	22.0
Hypersensitivity vasculitis	10020764	Narrow	16.0	17.0
Idiopathic urticaria	10021247	Narrow	16.0	16.0
Immediate post-injection reaction	10067142	Narrow	16.0	16.0
Immune thrombocytopenia	10083842	Narrow	23.0	23.0
Immune tolerance induction	10070581	Narrow	16.0	16.0
Implant site dermatitis	10063855	Narrow	16.0	16.0
Implant site hypersensitivity	10063858	Narrow	16.0	16.0
Implant site rash	10063786	Narrow	16.0	16.0
Implant site urticaria	10063787	Narrow	16.0	16.0
Incision site dermatitis	10073168	Narrow	16.0	16.0

Incision site rash	10073411	Narrow	16.0	16.0
Infusion related hypersensitivity reaction	10082742	Narrow	22.1	22.1
Infusion related reaction	10051792	Narrow	20.1	20.1
Infusion site dermatitis	10065458	Narrow	16.0	16.0
Infusion site eczema	10074850	Narrow	17.0	17.0
Infusion site hypersensitivity	10065471	Narrow	16.0	16.0
Infusion site rash	10059830	Narrow	16.0	16.0
Infusion site recall reaction	10076085	Narrow	18.1	18.1
Infusion site urticaria	10065490	Narrow	16.0	16.0
Infusion site vasculitis	10074851	Narrow	17.0	17.0
Injection related reaction	10071152	Narrow	20.1	20.1
Injection site dermatitis	10022056	Narrow	16.0	16.0
Injection site eczema	10066221	Narrow	18.0	18.0
Injection site hypersensitivity	10022071	Narrow	16.0	16.0
Injection site rash	10022094	Narrow	16.0	16.0
Injection site recall reaction	10066797	Narrow	18.1	18.1
Injection site urticaria	10022107	Narrow	16.0	16.0
Injection site vasculitis	10067995	Narrow	16.0	16.0
Instillation site hypersensitivity	10073612	Narrow	18.0	18.0
Instillation site rash	10073622	Narrow	18.0	18.0
Instillation site urticaria	10073627	Narrow	18.0	18.0
Interstitial granulomatous dermatitis	10067972	Narrow	16.0	16.0
Intestinal angioedema	10076229	Narrow	18.0	18.0
Iodine allergy	10052098	Narrow	16.0	16.0
Kaposi's varicelliform eruption	10051891	Narrow	16.0	16.0
Kounis syndrome	10069167	Narrow	16.0	16.0
Laryngeal oedema	10023845	Narrow	16.0	16.0
Laryngitis allergic	10064866	Narrow	16.0	16.0
Laryngospasm	10023891	Narrow	16.0	16.0
Laryngotracheal oedema	10023893	Narrow	16.0	16.0
Limbal swelling	10070492	Narrow	16.0	16.0
Lip oedema	10024558	Narrow	16.0	16.0
Lip swelling	10024570	Narrow	16.0	16.0
Mast cell degranulation present	10076606	Narrow	18.1	18.1
Medical device site dermatitis	10075572	Narrow	18.0	18.0
Medical device site eczema	10075575	Narrow	18.0	18.0
Medical device site hypersensitivity	10075579	Narrow	18.0	18.0
Medical device site rash	10075585	Narrow	18.0	18.0
Medical device site recall reaction	10076140	Narrow	18.1	18.1

Medical device site urticaria	10075588	Narrow	18.0	18.0
Mouth swelling	10075203	Narrow	17.1	17.1
Mucocutaneous rash	10056671	Narrow	16.0	16.0
Multiple allergies	10028164	Narrow	16.0	16.0
Nephritis allergic	10029120	Narrow	16.0	16.0
Nikolsky's sign	10029415	Narrow	16.0	16.0
Nodular rash	10075807	Narrow	18.0	18.1
Nutritional supplement allergy	10084049	Narrow	23.0	23.0
Oculomucocutaneous syndrome	10030081	Narrow	16.0	16.0
Oculorespiratory syndrome	10067317	Narrow	16.0	16.0
Oedema mouth	10030110	Narrow	16.0	16.0
Oral allergy syndrome	10068355	Narrow	16.0	16.0
Oropharyngeal blistering	10067950	Narrow	16.0	16.0
Oropharyngeal oedema	10078783	Narrow	20.0	20.0
Oropharyngeal spasm	10031111	Narrow	16.0	16.0
Oropharyngeal swelling	10031118	Narrow	16.0	16.0
Palatal oedema	10056998	Narrow	16.0	16.0
Palatal swelling	10074403	Narrow	17.0	17.0
Palisaded neutrophilic granulomatous dermatitis	10068809	Narrow	16.0	17.1
Palpable purpura	10056872	Narrow	16.0	16.0
Pathergy reaction	10074332	Narrow	17.0	17.0
Perioral dermatitis	10034541	Narrow	16.0	21.0
Periorbital oedema	10034545	Narrow	16.0	16.0
Periorbital swelling	10056647	Narrow	16.0	21.1
Pharyngeal oedema	10034829	Narrow	16.0	16.0
Pharyngeal swelling	10082270	Narrow	22.0	22.0
Procedural shock	10080894	Narrow	21.0	21.0
Pruritus allergic	10063438	Narrow	16.0	16.0
Radioallergosorbent test positive	10037789	Narrow	16.0	16.0
Rash	10037844	Narrow	16.0	16.0
Rash erythematous	10037855	Narrow	16.0	16.0
Rash follicular	10037857	Narrow	16.0	16.0
Rash macular	10037867	Narrow	16.0	16.0
Rash maculo-papular	10037868	Narrow	16.0	16.0
Rash maculovesicular	10050004	Narrow	16.0	16.0
Rash morbilliform	10037870	Narrow	16.0	16.0
Rash neonatal	10037871	Narrow	16.0	16.0
Rash papulosquamous	10037879	Narrow	16.0	16.0
Rash pruritic	10037884	Narrow	16.0	16.0
Rash pustular	10037888	Narrow	16.0	16.0

Rash rubelliform	10057984	Narrow	16.0	16.0
Rash scarlatiniform	10037890	Narrow	16.0	16.0
Rash vesicular	10037898	Narrow	16.0	16.0
Reaction to azo-dyes	10037973	Narrow	16.0	16.0
Reaction to colouring	10037974	Narrow	16.0	16.0
Reaction to excipient	10079925	Narrow	20.1	20.1
Reaction to food additive	10037977	Narrow	22.0	22.0
Reaction to preservatives	10064788	Narrow	16.0	16.0
Red man syndrome	10038192	Narrow	16.0	16.0
Rhinitis allergic	10039085	Narrow	16.0	16.0
Scleral oedema	10057431	Narrow	16.0	16.0
Scleritis allergic	10051126	Narrow	16.0	16.0
Scrotal dermatitis	10083260	Narrow	23.0	23.0
Scrotal oedema	10039755	Narrow	16.0	16.0
Serum sickness	10040400	Narrow	16.0	16.0
Serum sickness-like reaction	10040402	Narrow	16.0	16.0
Shock	10040560	Narrow	16.0	16.0
Shock symptom	10040581	Narrow	16.0	18.1
SJS-TEN overlap	10083164	Narrow	22.1	22.1
Skin necrosis	10040893	Narrow	16.0	16.0
Skin reaction	10040914	Narrow	16.0	16.0
Skin test positive	10040934	Narrow	16.0	16.0
Solar urticaria	10041307	Narrow	16.0	16.0
Solvent sensitivity	10041316	Narrow	16.0	16.0
Stevens-Johnson syndrome	10042033	Narrow	16.0	16.0
Stoma site hypersensitivity	10074509	Narrow	17.0	17.0
Stoma site rash	10059071	Narrow	17.0	17.0
Swelling face	10042682	Narrow	16.0	16.0
Swelling of eyelid	10042690	Narrow	16.0	21.1
Swollen tongue	10042727	Narrow	16.0	16.0
Symmetrical drug-related intertriginous and flexural exanthema	10078325	Narrow	19.1	19.1
Therapeutic product cross-reactivity	10079645	Narrow	20.1	20.1
Tongue oedema	10043967	Narrow	16.0	16.0
Toxic epidermal necrolysis	10044223	Narrow	16.0	16.0
Toxic skin eruption	10057970	Narrow	16.0	16.0
Tracheal oedema	10044296	Narrow	16.0	16.0
Type I hypersensitivity	10045240	Narrow	16.0	16.0
Type II hypersensitivity	10054000	Narrow	16.0	16.0

Type III immune complex mediated reaction	10053614	Narrow	16.0	16.0
Type IV hypersensitivity reaction	10053613	Narrow	16.0	16.0
Urticaria	10046735	Narrow	16.0	16.0
Urticaria cholinergic	10046740	Narrow	16.0	16.0
Urticaria chronic	10052568	Narrow	16.0	16.0
Urticaria contact	10046742	Narrow	16.0	16.0
Urticaria papular	10046750	Narrow	16.0	16.0
Urticaria physical	10046751	Narrow	16.0	16.0
Urticaria pigmentosa	10046752	Narrow	16.0	16.0
Urticaria vesiculosa	10046755	Narrow	16.0	16.0
Urticarial dermatitis	10082290	Narrow	22.0	22.0
Urticarial vasculitis	10048820	Narrow	16.0	19.0
Vaccination site dermatitis	10069477	Narrow	16.0	16.0
Vaccination site eczema	10076161	Narrow	18.1	18.1
Vaccination site exfoliation	10069489	Narrow	16.0	16.0
Vaccination site hypersensitivity	10068880	Narrow	16.0	16.0
Vaccination site rash	10069482	Narrow	16.0	16.0
Vaccination site recall reaction	10076188	Narrow	18.1	18.1
Vaccination site urticaria	10069622	Narrow	16.0	16.0
Vaccination site vasculitis	10076191	Narrow	18.1	18.1
Vaccination site vesicles	10069623	Narrow	16.0	16.0
Vaginal ulceration	10046943	Narrow	16.0	16.0
Vasculitic rash	10047111	Narrow	16.0	16.0
Vernal keratoconjunctivitis	10081000	Narrow	21.0	21.0
Vessel puncture site rash	10077117	Narrow	18.1	18.1
Vessel puncture site vesicles	10077813	Narrow	19.0	19.0
Vulval eczema	10066273	Narrow	16.0	22.1
Vulval ulceration	10047768	Narrow	16.0	16.0
Vulvovaginal rash	10071588	Narrow	16.0	16.0
Vulvovaginal ulceration	10050181	Narrow	16.0	16.0
Vulvovaginitis allergic	10080783	Narrow	21.0	21.0
Acute respiratory failure	10001053	Broad	16.0	16.0
Administration site photosensitivity reaction	10075961	Broad	18.0	18.0
Airway remodelling	10075289	Broad	17.1	17.1
Allergy to chemicals	10061626	Broad	16.0	16.0
Allergy to fermented products	10054929	Broad	16.0	16.0
Alpha tumour necrosis factor increased	10059982	Broad	16.0	16.0
Alveolitis	10001889	Broad	16.0	16.0
Antibody test abnormal	10061425	Broad	16.0	16.0

Antibody test positive	10061427	Broad	16.0	16.0
Anti-insulin antibody increased	10053815	Broad	16.0	16.0
Anti-insulin antibody positive	10053814	Broad	16.0	16.0
Anti-insulin receptor antibody increased	10068226	Broad	16.0	16.0
Anti-insulin receptor antibody positive	10068225	Broad	16.0	16.0
Application site photosensitivity reaction	10058730	Broad	18.0	18.0
Asthma	10003553	Broad	16.0	16.0
Asthma late onset	10003559	Broad	16.0	16.0
Asthma-chronic obstructive pulmonary disease overlap syndrome	10077005	Broad	18.1	18.1
Asthmatic crisis	10064823	Broad	16.0	16.0
Auricular swelling	10003800	Broad	16.0	16.0
Blister	10005191	Broad	16.0	16.0
Blister rupture	10073385	Broad	16.0	16.1
Blood immunoglobulin A abnormal	10005584	Broad	16.0	16.0
Blood immunoglobulin A increased	10005586	Broad	16.0	16.0
Blood immunoglobulin D increased	10063244	Broad	16.0	16.0
Blood immunoglobulin G abnormal	10005594	Broad	16.0	16.0
Blood immunoglobulin G increased	10005596	Broad	16.0	16.0
Blood immunoglobulin M abnormal	10005599	Broad	16.0	16.0
Blood immunoglobulin M increased	10005601	Broad	16.0	16.0
Bronchial hyperreactivity	10066091	Broad	16.0	16.0
Bronchial oedema	10056695	Broad	16.0	16.0
Bullous impetigo	10006563	Broad	16.0	16.0
Caffeine allergy	10074895	Broad	17.1	17.1
Capillaritis	10068406	Broad	16.0	16.0
Charcot-Leyden crystals	10008413	Broad	16.0	16.0
Cheilitis	10008417	Broad	22.0	22.0
Childhood asthma	10081274	Broad	21.1	21.1
Choking	10008589	Broad	16.0	16.0
Choking sensation	10008590	Broad	16.0	16.0
Complement factor C1 decreased	10051552	Broad	16.0	20.1

Complement factor C2 decreased	10051555	Broad	16.0	20.1
Complement factor C3 decreased	10050981	Broad	16.0	20.1
Complement factor C4 decreased	10050983	Broad	16.0	20.1
Complement factor decreased	10061048	Broad	16.0	20.1
Conjunctivitis	10010741	Broad	16.0	16.0
Corneal exfoliation	10064489	Broad	16.0	16.0
Cough variant asthma	10063076	Broad	16.0	23.0
Cytokine release syndrome	10052015	Broad	17.0	17.0
Cytokine storm	10050685	Broad	17.0	17.0
Ear swelling	10014025	Broad	16.0	16.1
Eosinophil count abnormal	10061125	Broad	16.0	16.0
Eosinophil count increased	10014945	Broad	16.0	16.0
Eosinophil percentage abnormal	10058133	Broad	16.0	16.0
Eosinophil percentage increased	10052222	Broad	16.0	16.0
Eosinophilia	10014950	Broad	16.0	16.0
Eosinophilia myalgia syndrome	10014952	Broad	16.0	16.0
Eosinophilic bronchitis	10065563	Broad	16.0	16.0
Eosinophilic oesophagitis	10064212	Broad	16.0	16.0
Eosinophilic pneumonia	10014962	Broad	16.0	16.0
Eosinophilic pneumonia acute	10052832	Broad	16.0	16.0
Eosinophilic pneumonia chronic	10052833	Broad	16.0	16.0
Erythema	10015150	Broad	16.0	16.0
Flushing	10016825	Broad	16.0	16.0
Gastrointestinal oedema	10058061	Broad	16.0	16.0
Generalised oedema	10018092	Broad	16.0	16.0
Genital rash	10018175	Broad	16.0	16.0
Genital swelling	10067639	Broad	16.0	16.0
Haemolytic transfusion reaction	10067122	Broad	16.0	16.0
HLA marker study positive	10067937	Broad	16.0	16.0
Human anti-hamster antibody increased	10082107	Broad	22.0	22.0
Human anti-hamster antibody positive	10082109	Broad	22.0	22.0
Immune complex level increased	10064650	Broad	16.0	16.0
Immunoglobulins abnormal	10021497	Broad	16.0	16.0
Immunoglobulins increased	10021500	Broad	16.0	16.0
Immunology test abnormal	10061214	Broad	16.0	16.0
Implant site photosensitivity	10073415	Broad	18.0	18.0
Infusion site photosensitivity reaction	10065486	Broad	18.0	18.0
Injection site panniculitis	10083040	Broad	22.1	22.1

Injection site photosensitivity reaction	10053396	Broad	18.0	18.0
Interstitial lung disease	10022611	Broad	16.0	16.0
Laryngeal dyspnoea	10052390	Broad	16.0	16.0
Laryngeal obstruction	10059639	Broad	16.0	16.0
Leukotriene increased	10064663	Broad	16.0	16.0
Lip exfoliation	10064482	Broad	16.0	16.0
Localised oedema	10048961	Broad	16.0	16.0
Macrophage inflammatory protein-1 alpha increased	10083049	Broad	22.1	22.1
Mechanical urticaria	10068773	Broad	16.0	16.0
Medical device site photosensitivity reaction	10076137	Broad	18.0	18.0
Mesenteric panniculitis	10063031	Broad	16.0	16.0
Monocyte chemotactic protein-2 increased	10083043	Broad	22.1	22.1
Mouth ulceration	10028034	Broad	16.0	16.0
Mucocutaneous ulceration	10028084	Broad	16.0	16.0
Mucosa vesicle	10028103	Broad	16.0	16.0
Mucosal erosion	10061297	Broad	16.0	16.0
Mucosal exfoliation	10064486	Broad	16.0	16.0
Mucosal necrosis	10067993	Broad	16.0	16.0
Mucosal ulceration	10028124	Broad	16.0	16.0
Nasal crease	10078581	Broad	19.1	19.1
Necrotising panniculitis	10062579	Broad	16.0	16.0
Neurodermatitis	10029263	Broad	16.0	16.0
Neutralising antibodies positive	10064980	Broad	16.0	16.0
Noninfective conjunctivitis	10074701	Broad	17.0	17.0
Non-neutralising antibodies positive	10064982	Broad	16.0	16.0
Occupational asthma	10070836	Broad	16.0	16.0
Occupational dermatitis	10030012	Broad	16.0	16.1
Oedema mucosal	10030111	Broad	16.0	16.0
Oral mucosal exfoliation	10064487	Broad	16.0	16.0
Orbital oedema	10031051	Broad	16.0	16.0
Panniculitis	10033675	Broad	16.0	16.0
Penile exfoliation	10064485	Broad	16.0	16.0
Penile oedema	10066774	Broad	16.0	16.0
Penile rash	10082571	Broad	22.1	22.1
Penile swelling	10034319	Broad	16.0	16.0
Perineal rash	10075364	Broad	17.1	17.1
Perivascular dermatitis	10064986	Broad	16.0	16.0

Photosensitivity reaction	10034972	Broad	16.0	16.0
Pneumonitis	10035742	Broad	16.0	16.0
Prurigo	10037083	Broad	16.0	16.0
Pruritus	10037087	Broad	16.0	16.0
Pulmonary eosinophilia	10037382	Broad	16.0	16.0
Reactive airways dysfunction syndrome	10070832	Broad	16.0	16.0
Respiratory arrest	10038669	Broad	16.0	16.0
Respiratory distress	10038687	Broad	16.0	16.0
Respiratory failure	10038695	Broad	16.0	16.0
Respiratory tract oedema	10070774	Broad	16.0	16.0
Reversible airways obstruction	10062109	Broad	16.0	16.0
Rhinitis perennial	10039094	Broad	16.0	16.0
Scrotal exfoliation	10081178	Broad	21.1	21.1
Scrotal swelling	10039759	Broad	16.0	16.0
Seasonal allergy	10048908	Broad	16.0	16.0
Septal panniculitis	10056876	Broad	16.0	16.0
Skin erosion	10040840	Broad	16.0	16.0
Skin exfoliation	10040844	Broad	16.0	16.0
Skin oedema	10058679	Broad	16.0	16.0
Skin swelling	10053262	Broad	16.0	16.0
Sneezing	10041232	Broad	16.0	16.0
Status asthmaticus	10041961	Broad	16.0	16.0
Stomatitis	10042128	Broad	16.0	16.0
Streptokinase antibody increased	10053797	Broad	16.0	16.0
Stridor	10042241	Broad	16.0	16.0
Suffocation feeling	10042444	Broad	16.0	16.0
Sunscreen sensitivity	10083629	Broad	23.0	23.0
Throat tightness	10043528	Broad	16.0	16.0
Tongue exfoliation	10064488	Broad	16.0	16.0
Tracheal obstruction	10044291	Broad	16.0	16.0
Tracheostomy	10044320	Broad	16.0	16.0
Transplantation associated food allergy	10075008	Broad	17.1	17.1
Upper airway obstruction	10067775	Broad	16.0	16.0
Vaccination site photosensitivity reaction	10076186	Broad	18.0	18.0
Vaginal oedema	10063818	Broad	16.0	16.0
Visceral oedema	10065768	Broad	16.0	16.0
Vulval oedema	10047763	Broad	16.0	16.0
Vulvovaginal exfoliation	10083435	Broad	23.0	23.0
Vulvovaginal swelling	10071211	Broad	16.0	16.0

Wheezing	10047924	Broad	16.0	16.0

APPENDIX III STANDARDIZED MEDDRA QUERIES (SMQ) FOR ANAPHYLACTIC REACTION

MedDRA 23.0: Anaphylactic reaction (SMQ) Preferred Term	Code	Scope	Category	Addition Version	Last Modified Version
Anaphylactic reaction	10002198	Narrow	A	8.1	8.1
Anaphylactic shock	10002199	Narrow	A	8.1	8.1
Anaphylactic transfusion reaction	10067113	Narrow	A	11.1	11.1
Anaphylactoid reaction	10002216	Narrow	A	8.1	8.1
Anaphylactoid shock	10063119	Narrow	A	8.1	8.1
Circulatory collapse	10009192	Narrow	A	8.1	8.1
Dialysis membrane reaction	10076665	Narrow	A	18.1	18.1
Kounis syndrome	10069167	Narrow	A	12.0	12.0
Procedural shock	10080894	Narrow	A	21.0	21.0
Shock	10040560	Narrow	A	8.1	8.1
Shock symptom	10040581	Narrow	A	8.1	18.1
Type I hypersensitivity	10045240	Narrow	A	8.1	8.1
Acute respiratory failure	10001053	Broad	B	8.1	8.1
Asthma	10003553	Broad	B	8.1	8.1
Bronchial oedema	10056695	Broad	B	8.1	8.1
Bronchospasm	10006482	Broad	B	8.1	8.1
Cardio-respiratory distress	10049874	Broad	B	8.1	8.1
Chest discomfort	10008469	Broad	B	8.1	8.1
Choking	10008589	Broad	B	8.1	8.1
Choking sensation	10008590	Broad	B	8.1	8.1
Circumoral oedema	10052250	Broad	B	11.0	11.0
Cough	10011224	Broad	B	8.1	8.1
Cough variant asthma	10063076	Broad	B	8.1	23.0
Cyanosis	10011703	Broad	B	14.1	15.0
Dyspnoea	10013968	Broad	B	8.1	8.1
Hyperventilation	10020910	Broad	B	8.1	8.1
Irregular breathing	10076213	Broad	B	18.0	18.1
Laryngeal dyspnoea	10052390	Broad	B	8.1	8.1
Laryngeal oedema	10023845	Broad	B	8.1	8.1
Laryngospasm	10023891	Broad	B	8.1	8.1
Laryngotracheal oedema	10023893	Broad	B	8.1	8.1
Mouth swelling	10075203	Broad	B	17.1	17.1
Nasal obstruction	10028748	Broad	B	12.1	14.0
Oedema mouth	10030110	Broad	B	8.1	8.1
Oropharyngeal oedema	10078783	Broad	B	20.0	20.0

Oropharyngeal spasm	10031111	Broad	B	8.1	8.1
Oropharyngeal swelling	10031118	Broad	B	8.1	8.1
Pharyngeal oedema	10034829	Broad	B	20.0	20.0
Pharyngeal swelling	10082270	Broad	B	22.0	22.0
Respiratory arrest	10038669	Broad	B	8.1	8.1
Respiratory distress	10038687	Broad	B	8.1	8.1
Respiratory failure	10038695	Broad	B	8.1	8.1
Reversible airways obstruction	10062109	Broad	B	8.1	8.1
Sensation of foreign body	10061549	Broad	B	8.1	8.1
Sneezing	10041232	Broad	B	8.1	8.1
Stridor	10042241	Broad	B	8.1	8.1
Swollen tongue	10042727	Broad	B	8.1	8.1
Tachypnoea	10043089	Broad	B	14.1	14.1
Throat tightness	10043528	Broad	B	8.1	8.1
Tongue oedema	10043967	Broad	B	8.1	8.1
Tracheal obstruction	10044291	Broad	B	8.1	8.1
Tracheal oedema	10044296	Broad	B	8.1	8.1
Upper airway obstruction	10067775	Broad	B	11.0	11.0
Wheezing	10047924	Broad	B	8.1	8.1
Acquired C1 inhibitor deficiency	10081035	Broad	C	21.0	21.0
Allergic oedema	10060934	Broad	C	8.1	8.1
Angioedema	10002424	Broad	C	8.1	10.0
Circumoral swelling	10081703	Broad	C	21.1	21.1
Erythema	10015150	Broad	C	8.1	8.1
Eye oedema	10052139	Broad	C	8.1	8.1
Eye pruritus	10052140	Broad	C	14.1	14.1
Eye swelling	10015967	Broad	C	8.1	8.1
Eyelid oedema	10015993	Broad	C	8.1	8.1
Face oedema	10016029	Broad	C	8.1	8.1
Flushing	10016825	Broad	C	8.1	8.1
Hereditary angioedema with C1 esterase inhibitor deficiency	10080955	Broad	C	21.0	21.0
Injection site urticaria	10022107	Broad	C	14.1	14.1
Lip oedema	10024558	Broad	C	8.1	9.1
Lip swelling	10024570	Broad	C	8.1	9.1
Nodular rash	10075807	Broad	C	18.0	18.1
Ocular hyperaemia	10030041	Broad	C	14.1	14.1
Oedema	10030095	Broad	C	8.1	8.1
Oedema blister	10080039	Broad	C	20.1	20.1
Periorbital oedema	10034545	Broad	C	8.1	8.1
Periorbital swelling	10056647	Broad	C	8.1	21.1

Pruritus	10037087	Broad	C	8.1	8.1
Pruritus allergic	10063438	Broad	C	8.1	8.1
Rash	10037844	Broad	C	8.1	8.1
Rash erythematous	10037855	Broad	C	8.1	8.1
Rash pruritic	10037884	Broad	C	8.1	8.1
Skin swelling	10053262	Broad	C	8.1	8.1
Swelling	10042674	Broad	C	8.1	8.1
Swelling face	10042682	Broad	C	8.1	8.1
Swelling of eyelid	10042690	Broad	C	8.1	21.1
Urticaria	10046735	Broad	C	8.1	8.1
Urticaria papular	10046750	Broad	C	8.1	8.1
Blood pressure decreased	10005734	Broad	D	8.1	8.1
Blood pressure diastolic decreased	10005737	Broad	D	8.1	8.1
Blood pressure systolic decreased	10005758	Broad	D	8.1	8.1
Cardiac arrest	10007515	Broad	D	8.1	8.1
Cardio-respiratory arrest	10007617	Broad	D	8.1	8.1
Cardiovascular insufficiency	10065929	Broad	D	9.0	9.0
Diastolic hypotension	10066077	Broad	D	9.1	9.1
Hypotension	10021097	Broad	D	8.1	9.1
Hypotensive crisis	10083659	Broad	D	23.0	23.0
Post procedural hypotension	10084013	Broad	D	23.0	23.0

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